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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,498	01/16/2004	Melvin Dorin	1754A-008 C1 (81841.0251)	7662
46267	7590	05/09/2006	EXAMINER	
HOGAN & HARTSON LLP 500 S GRAND AVE SUITE 1900 LOS ANGELES, CA 90071				
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/759,498

Applicant(s)

DORIN ET AL.

Examiner

David A. Reifsnyder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-10,13,14 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,6,9,10 and 46-49 is/are allowed.
- 6) ☒ Claim(s) 1,3,7,8,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishimaru et al.

Regarding claims 1, 3 and 13; Ishimaru et al. discloses a removable polyolefin polymer liner (64) for a centrifuge container (16) having an interior cavity (54, 56) and an opening, the removable polyolefin polymer liner (64) comprising: a disposable flexible, semi-rigid body with an opening (76) for introducing a sample, wherein the disposable flexible, semi-rigid body of the removable polyolefin polymer liner (64) conforms to the interior cavity of the centrifuge container (16), once inside the centrifuge container (16). (Figs. 2,3 and 5)

Claims 1, 3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenhalgh.

Regarding claims 1, 3 and 14; Greenhalgh discloses a removable liner (20) for a container (10) having an interior cavity and an opening, the removable liner (20) comprising: a disposable flexible, semi-rigid pre-sterilized (col. 2, line 2) body with an opening for introducing a fluid, a plurality of pleated strengthening structures (22) integrally formed on a side wall of the disposable flexible, semi-rigid pre-sterilized (col.

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2, line 2) body of the removable liner (20) for strengthening the disposable flexible, semi-rigid pre-sterilized body of the removable liner (20), wherein the disposable flexible, semi-rigid body pre-sterilized body of the removable liner (20) conforms to the interior cavity of the container (10), once inside the container (10).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishimaru et al.

Regarding claims 7 and 8; Ishimaru et al. discloses an o-ring for providing a seal between his removable liner and his centrifuge container but fails to disclose that the o-ring is integrally formed with the body of his removable liner. It is considered that it would have been obvious to one having ordinary skill in the art at the time of the invention to have made Ishimaru et al.'s o-ring integral with his body of his removable liner for ease of assembly of the o-ring between Ishimaru et al.'s removable liner and his centrifuge container, and to create a good seal between Ishimaru et al.'s removable liner and his centrifuge container. Regarding claim 14: Ishimaru et al. discloses that claimed invention except for his liner being pre-sterilized. It is considered that it would have been obvious to one having ordinary skill in the art at the time of the invention that Ishimaru et al.'s liner is pre-sterilized so that his biological fluids to be separated do not become contaminated.

***Allowable Subject Matter***

Claims 9, 10, 5, 6 and 46-48 are allowed.

The reason for the allowance of claims 9, 10, 5, 6 and 46-48 can be found on page 8, lines 6-17 of the applicants' remarks filed on January 16, 2004.

### ***Response to Arguments***

Applicant's arguments filed on April 28, 2006 have been fully considered but in regards to claims 1, 3, 7, 8, 13 and 14 they are not persuasive.

Regarding claims 1, 3, 7, 8, 13 and 14; the applicant argues on pages 6 and 7 of his remarks in the section labeled (1), that Ishimaru et al. does not teach that the body of liner (64) conforms to the interior cavity of a centrifuge container, once inside the container, as required by claim 1. However, Ishimaru et al. teaches on col. 4, lines 37-46 a liner (64) which is made of a material which **would** conform to the centrifuge container's inner cavity, once inside the container. A spring (see fig. 4) keeps the liner (64) from conforming to the centrifuge container's inner cavity until the centrifuge starts, and allows the liner (64) to spring back when the centrifuge stops (see fig. 4).

Furthermore, Ishimaru et al.'s liner (64) does not have to conform to the interior cavity of the centrifuge container because the centrifuge container has not been claimed. The liner (64) conforming to the centrifuge container's interior cavity is the **intended use** of the liner. The liner (64) is **capable** of conforming to the interior cavity of the centrifuge container, before centrifugation of the container. Furthermore, while it is believed that Ishimaru et al. discloses a liner (64) which **would** conform or at least be **capable** of conforming to the interior cavity of his centrifuge container before centrifugation (i.e. once inside the container), it is not believed that claim 1 excludes liners which only conform to the interior cavity of a centrifuge after centrifugation. Lastly, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus

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satisfying the claimed structural limitations. *Ex parte Masham, 2 USPQ2d 1647 (1987).*

Regarding claims 1, 3 and 14; the applicant argues on page 7 of his remarks in the section labeled (2), remarks that Greenhalgh does not teach a liner that conforms to the interior cavity of a container, once inside the container, as required by claim 1. Furthermore, the applicant argues that Greenhalgh teaches a liner that conforms to the interior cavity of a container, only when the liner is filled with a liquid. It is true that Greenhalgh teaches on col. 1, lines 20-23 that his liner (20) conforms to the interior cavity once the container is filled with liquid. However, that means that Greenhalgh's liner (20) is made of a material that with some manipulation conforms to the interior cavity of the container, once inside the container. Furthermore, Greenhalgh's liner (20) does not have to conform to the interior cavity of the container because the container has not been claimed. The liner (20) conforming to the container's interior cavity is the **intended use** of the liner. The liner (20) is **capable** of conforming to the interior cavity of the centrifuge container, before adding liquid to the container. Furthermore, while it is believed that Greenhalgh discloses a liner which **would** conform or at least be **capable** of conforming to the interior cavity of his container before adding liquid to the container (i.e. once inside the container), it is not believed that claim 1 excludes liners which only conform to the interior cavity of a container after adding liquid to the container. Lastly, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art

apparatus satisfying the claimed structural limitations. *Ex parte Masham, 2 USPQ2d 1647 (1987).*

### ***Final Rejection***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Reifsnnyder whose telephone number is (571) 272-1145. The examiner can normally be reached on M-F 9:00 AM to 5:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda M. Walker can be reached on (571) 272-1151. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David A Reifsnyder  
Primary Examiner  
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DAR